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TAILINGS
PROGRAM

Canada

A Discussion Paper on De Minimis (or Trivial) Levels of Contaminant Concentrations or Doses

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PREFACE

Whether viewed within a specific context such as uranium tailings management or applied to a pervasive issue such as regulatory reform, the de minimis concept is an elusive, almost enigmatic collection of ideas. On one hand, it has the appearance of being easy to understand, it is an intuitive part of personal decision making, and it has been implicitly part of laws and regulations for many years. On the other hand, it may be incompatible with some existing regulations and require a rethinking of the basic philosophy underlying a number of social practices.

To study the possible role of the de minimis concept in the management of uranium tailings, a team of individuals was assembled with representatives from the disciplines of engineering, science, law, medicine, economics, ethics and philosophy. The report produced by the team draws together ideas and opinions from a patchwork of sources that illustrates the multidisciplinary and formative nature of this complex subject.

As in any collective effort, an element of compromise and concession was required to form all of the member's contributions into the final product. Decisions as to which points were included and the manner in which they were expressed ultimately resided with the editors. While consensus was reached in many areas, the report should not be interpreted as representing the views of all team members for all of the topics addressed.

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SUMMARY

The term de minimis has its origins in several Latin phrases that are often used to explain points of law. One example is the phrase de minimis non curat lex which can be translated as "the law does not concern itself with trifles." The essence of the de minimis concept is that there are conditions that are perceived to be insignificant because the risks they present are so small. In uranium tailings management, the de minimis concept might be a valuable guide in evaluating the acceptability of management techniques and assessing the potential effects imposed on man and the environment.

The de minimis concept has long been part of many laws and regulations. Indeed, all organizations that have risk management responsibilities use the de minimis concept because resources are always finite and the supply of very small risks is virtually inexhaustible. That society has decided to tolerate exposures to various substances (or recognized the unavoidability of some exposure) is evident in several types of legislation such as drinking water criteria, air quality criteria, and food and drug regulations. Radiation protection agencies in Canada and the United States have used the essence of the de minimis concept by ruling that certain low level radioactive sources such as scintillation fluids and ionization-chamber smoke detectors can be placed in unlicensed waste disposal facilities.

The prime advantage often attributed to the de minimis concept is that it can prevent the spending of society's resources (which are finite) on insignificant matters to the detriment of those more deserving. The concept can also be used to circumvent the assessment of effects so small or improbable that the uncertainty inherent in the assessment techniques being used makes the estimates of the results unreliable. Similarly, the application of the concept has been cited as a way to rationalize the regulatory process by making it more consistent, cost effective, equitable and predictable.

Despite the fact that the essence of the de minimis concept is implicitly part of many regulations, it does not appear to fit cleanly into current health protection philosophy. More importantly, it appears that before it can fit explicitly, considerable change will be needed in the attitudes of society and its regulators. Some might argue that the concept represents nothing more than a call for a more pragmatic approach, while opponents could argue that adoption of the de minimis concept would signal a possible reduction in health protection for all members of the population in general, and hypersensitive individuals in particular.

Should the de minimis concept become widely accepted by society as meriting explicit inclusion in regulations, many existing regulations could be affected. The explicit incorporation of the de minimis concept into any code of practice (such as that for uranium tailings management) could draw attention to the implicit de minimis values found in other pieces of legislation. Investigation would most likely reveal that the implicit de minimis values are inconsistent in the degrees of health protection they offer. In turn, this could lead to calls to re-establish all the de minimis levels (implicit and explicit) using a consistent methodology and generating a consistent level of protection. While beneficial in the long run, the process of achieving this consistency could be traumatic.

The de minimis concept appears to offer several opportunities for improving the effectiveness of health protection (or risk regulation). Three examples of potential economic benefits include the elimination of wasteful practices in handling, shipping and disposing of low-level waste material; more effective use of special disposal repositories; and, relief to regulators and industry from the monitoring, record keeping and assessment of trivial matters. The net result could be savings to the generators of de minimis materials and their shareholders, potential savings to their customers, the ability of regulators to shift resources to more pressing matters, and savings to the source of regulatory funding, the public.

Many of the same considerations relevant to the philosophy, administration, and economic issues of health protection are also relevant to the ethical issues. A strong case can be made for stating that it can never be morally obligatory to waste resources, and that below certain levels of risk, the benefits to be derived from further attention to certain conditions or concentrations are so minute that expending resources on those conditions or concentrations would be wasteful regardless of the way benefits are defined. Often the costs of even investigating a substance would be greater than the maximum potential benefits derived from doing something about it. This and many other considerations support the conclusion that adopting a de minimis concept is morally justified if correctly defined.

Based on these considerations, two general applications are identified for the de minimis concept in the management of uranium tailings. The first role is to evaluate specific management practices by comparing the dose to the critical receptor to the de minimis value. If the de minimis value is greater than the receptor's dose, no further health protection effort is needed. The second application is for the de minimis value to identify the point of truncation, either in time or space, of dose or risk. Both of these applications place limits on the efforts used in ALARA-type calculations.

One possible form the application of the de minimis concept to uranium tailings management could take is as follows:

- de minimis levels of risk would be defined for individual dose and for truncating collective dose estimates, the former being the greater of the two since the possibility of exposure to more than one source would be greater for a group than an individual.
- both de minimis risk levels would be translated to exposures or doses;
- to evaluate a specific practice, all pertinent pathways would be analyzed for the critical receptor and if the exposures were less than the de minimis value for the individual, no further effort would be needed for exposure reduction;
- if pathways analysis indicated that exposures greater than the individual de minimis level could be anticipated, the second de minimis value would be used to identify the appropriate point of truncation in time or space for estimates of collective dose.

This process could be applied in principle to either radioactive or non-radioactive releases.

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1.0 INTRODUCTION

1.1 Study Objectives

In 1982, the Government of Canada announced the National Uranium Tailings Program (NUTP). The main objective of the program is to provide scientific information that will assist in the establishment of long-term management strategies for uranium tailings. Part of this effort is directed towards improving the assessment of the potential effects that uranium tailings can impose on man and the environment.

Uranium tailings areas can release to the environment both radioactive and non-radioactive substances. The resulting exposures vary according to many factors including receptor location, habits and time. Using theoretical techniques, assessments of exposures can be extended, in concept at least, almost indefinitely to include immense populations (entire continents or larger) and exposure periods of many centuries or millenia. This leads to the consideration of increasingly smaller individual exposures and, ultimately, to the requirement for some boundary or limit to cut off or truncate dose assessments. Most often, the assessment limits have taken the form of arbitrarily selected cut-off values of distance or time.

One less arbitrary approach in such assessments is to truncate the estimation of dose at the point where exposures are considered to present an insignificant or trivial level of risk. The philosophy that there is such a level of risk is referred to as the de minimis concept. The examination of the de minimis concept and its possible application to the assessment of uranium tailings management strategies is the objective of this study.

To undertake the study, the NUTP directed SENES Consultants Limited to prepare a discussion paper concerning the methodology of establishing de minimis levels of contaminant concentrations or doses arising from uranium tailings. While the implications of applying the concept to tailings management was to be the ultimate focus of the study, the NUTP identified other related topics to be addressed including the ideas and reasoning underlying the concept, and the use of similiar concepts in other aspects of life. The study's orientation was to be directed more towards examining the philosophy and principles of the concept rather than attempting to quantify specific de minimis levels.

1.2 Study Approach

Recognizing that the study of the de minimis concept requires the consideration of a wide spectrum of information sources, interests and concerns, SENES assembled a team of individuals from various disciplines including engineering, science, law, medicine, economics, ethics and philosophy.

To prepare the discussion document, the study team adopted an approach that consisted of four general tasks. The first task was to prepare an initial essay about the de minimis concept based on a review of pertinent literature. The initial essay was distributed to team members for their critical review. At the same time, members were also asked to identify key references that they felt illustrate important aspects of the concept.

The second task was to improve and expand upon the initial essay to produce a final draft of the discussion paper. The comments and critiques of the initial essay and the references suggested by the team members were considered. The findings of similar efforts being undertaken elsewhere were discussed with several

individuals involved in those projects.

The third task was a workshop at which team members and invited guests discussed various aspects of the concept and the contents of the first draft.

For the final task, the first draft was modified based on the workshop discussions to produce the second draft. Comments from team members concerning the second draft were considered in the production of the report.

1.3 Report Organization

This report has been organized into a series of discussions that address the following sequence of questions:

- -What is the de minimis concept and what does it mean?
- -Has it been used before and if so, how?
- -What are the pros and cons of using it?
- -How might it be applied to uranium tailings management?

Accordingly, Chapter 2.0 is a discussion of the origin of the de minimis concept. The ways in which the essence of the concept has been used in various types of legislation are also described.

Chapter 3.0 presents a review of the advantages and disadvantages of explicitly incorporating the de minimis concept into regulations including those that address uranium tailings. Philosophical, administrative, economic, ethical and technical considerations are addressed.

In Chapter 4.0, some possible roles for the de minimis concept in uranium tailings management are discussed. The relationships

between de minimis and other regulatory concepts such as the ALARA principle are described.

Several appendices supplement the main body of the report. Appendix A is a list of the team members, workshop guests, and others contacted during the course of the study.

Some of the approaches that have been suggested as ways of quantifying de minimis values are reviewed in Appendix B. Although mention is made of both radioactive and non-radioactive substances, much of the pertinent literature concerning this aspect of the concept comes from studies of the health effects associated with exposure to ionizing radiation.

Appendix C is a review of the current positions of several regulatory agencies regarding the de minimis concept. Canadian, American and international agencies are included.

Appendix D is an annotated bibliography of key references that team members felt provide valuable insights into the de minimis concept and related topics.

Appendix E is a brief summary of several items identified during the study workshop as being of potential interest for future study.

1.4 Fundamental Issues Beyond the Scope of this Study

While directed to investigate the possible application of the de minimis concept to the management of uranium tailings, the team often found itself being drawn into more fundamental issues such as the general philosophy of health protection regulation, and the inconsistencies that exist between the legislation for long-established practices and those for new or proposed undertakings.

While the team recognized that such issues are integral to understanding the full implications of the de minimis concept, to address them in detail was beyond the scope and resources of this study.

As a compromise, these important topics are touched upon briefly in Chapters 2.0 and 3.0. In some instances, these considerations touch upon broad moral and socio-economic issues which, in the final analysis, came to define areas into which the resources of the study did not permit passage; however, their intluences can be seen throughout the report.

2.0 TRADITIONAL ASPECTS OF THE DE MINIMIS CONCEPT

2.1 Origin

The term de minimis has its origins in several Latin phrases that are often used to explain points of law. One example is the phrase de minimis non curat lex which can be translated as "the law does not concern itself with trifles". The essence of the de minimis concept is that there are conditions that are perceived to be insignificant because the risks they present are so small.

De minimis conditions do not influence people's behaviour. They are perceived as presenting no concern and hence are ignored. For example, many people will take an aspirin or go for a ride in a car without thinking of the risks involved. To those people, those risks have been judged to be insignificant or de minimis levels of risk.

The essence of the de minimis concept has long been part of many laws and regulations. Indeed, all organizations that have risk management responsibilities use the de minimis concept because resources are always finite and the supply of very small risks is virtually inexhaustible (Whipple, 1984). Its existence stems from decisions that, for many issues, there can come a time or place at which it no longer is efficient or beneficial to pursue matters further. Thus legal descriptions of properties have distances accurate to within 10 millimetres, tax refunds or payments of less than one dollar are waived, and trace amounts of foreign matter are allowed in food products.

2.2 Relationship to Risk Management

In Canada, as in many countries, health protection agencies are directed to curtail or eliminate exposures to certain substances and conditions. Regulations and agency mandates that address this ideal often use vague terms such as poisonous, harmful, deleterious, hazardous, or injurious to describe the substances and conditions in question.

Historically the definitions assigned to such terms have emerged from deliberations that considered, among other things, detectability, background concentrations or natural presence, acceptability, known and perceived health effects, legal precedence and public expectations. Given that many of these factors and the relative importance assigned to each involve subjective judgements, it is not suprising that these deliberations have produced definitions that vary from substance to substance, jurisdiction to jurisdiction, and with time.

Common to all health protection efforts is the element of risk. In fact, there are many common elements in the meanings of the terms "health protection" and "risk regulation". In recent years, risk regulation has become a widely used term that includes many of the traditional aspects of health protection to the extent that the balancing of health and other benefits against perceived risks has become a central issue in developing regulatory policy (Munro and Krewski, 1981). Key aspects of risk regulation include defining and quantifying risks, comparing risks to one another, identifying those at risk, determining acceptable levels of risk, and trying to reduce risks.

Risk is usually interpreted to mean the chance of encountering harm or loss. Although trite, it is nevertheless true that all activities entail some risk, and people perform their own risk

assessments frequently and often intuitively. Health risks are frequently quantified in statistical parameters such as days of life expectancy lost or annual probability of death associated with a certain activity.

Out of prudence, it is often assumed that risks do not have thresholds; that is, regardless how small a dose or exposure may be, there is some risk of adverse effects. This leaves regulators (and society) in a quandary for if the relation of adverse effects and dose has a zero intercept, then attention must focus on determining acceptable (non-zero) risks. This is the no-threshold hypothesis which is described in Section 3.2

Most individuals (including regulators) are unfamiliar and even uncomfortable with the quantification of risk; however, the assumed absence of thresholds necessitates the quantification of extremely small risks. Thus, the absence of thresholds complicates risk management. In this context, the de minimis concept can offer thresholds of policy to use in place of scientific thresholds (Whipple, 1984).

For various reasons, radiation protection has borne the brunt of advancing relatively new ideas including several pertaining to risk regulation such as the application of the de minimis concept (Pochin, 1984). Unlike other aspects of health protection, the health physics profession has recognized and tried for many decades to predict the occurrence of delayed effects or those resulting from chronic, low exposures. So too has the discipline of radiation protection taken the lead in identifying acceptable levels of risk and in developing risk management policies. Not surprisingly, it is the major source of studies that explictly address the de minimis concept and its possible applications.

Surveys of risks associated with various activities indicate that a one-in-a-million (10^{-6}) chance per year of death is often regarded as an insignificant level of risk, primarily because it is extremely small compared with the risk of death from many other causes (Webb and McLean, 1977). For example, the most risk-free age group of Canadian males is the 5 to 15 years old cohort. To an individual in that group, the annual risk of death from all causes is approximately 450 chances per million (Cherry and Colburn, 1973). For individuals in the 55 to 65 age bracket, when the risks of cancer and heart disease typically become prominent, the annual risk of death is approximately 14,000 per million. The annual risk of death averaged over all age groups is approximately 7,300 per million.

From the work of several researchers (Oser, 1978; Wilson, 1979; Starr and Whipple, 1980; Pochin, 1978a), further perspective on the meaning of a one-in-a-million annual risk of death can be obtained by considering a few other conditions and activities that are estimated to produce that level of risk. Some of these estimates, obtained using various mathematical procedures, are shown in Table 2.1.

Other researchers have suggested that risk becomes insignificant at higher or lower levels, with many of these estimates lying in the range of 10^{-5} to 10^{-7} per year. All researchers agree that the appreciation of risk is highly subjective, varies from person to person, and depends on many factors. A de minimis value for the risk of death of 10^{-6} per year is one of the most frequently encountered values in the literature.

While the magnitudes of risks are one basis for making comparisons between activities or conditions, other factors also need to be considered before risks can be called similar. These include the way the risk is imposed, whether or not it is

Table 2.1

SELECTED ACTIVITIES WITH A RISK OF DEATH OF ONE IN A MILLION

Activity	Cause of Death
Travelling 50 miles by car	Accident
Travelling 10 miles by bicycle	Accident
Living 2 months in a stone or brick house	Cancer from natural radioactivity
Living 2 months with a cigarette smoker	Cancer, heart disease
Smoking 1 cigarette	Cancer, heart disease
Drinking 0.6 ounces of beer per day for a year	Cancer (alcohol-related)
Drinking 2 ounces of milk per day for a year	Cancer (aflatoxin-related)
Living 20 minutes at the age of 60	All causes

avoidable, and whether it involves a fatality, disease or disability (Pochin, 1984). These sorts of considerations complicate the identification and acceptance of de minimis levels of risk. Ultimately, the definition is a societal decision.

2.3 Role in the Legislation of Non-radioactive Substances

That society has decided to tolerate exposures to various substances (or recognized the unavoidability of some exposure) is evident in several types of legislation such as drinking water criteria, air quality criteria, and food and drug regulations. Recent U.S. Environmental Protection Agency (EPA) water quality criteria reviews identify concentrations corresponding to different levels of risk, explicitly acknowledging that even the most stringent proposed concentration still presents a theoretically quantifiable risk, albeit possibly trivial or inconsequential, to the water user.

Similarly, the U.S. Food and Drug Administration (FDA) has determined that a risk of death of one in one million over a lifetime imposes no significant additional risk of cancer to the public. The FDA has concluded that a lower risk would not significantly increase the protection of public health, but would probably prohibit the use of most animal drugs or feed additives (U.S. FDA, 1979).

Paracelsus, a sixteenth century physician, is often credited with the discovery that every substance can be toxic under certain conditions. His proposition, originally stated in German was: "What is it that is not poison? Only the dose determines that a thing is no poison." Repeatedly translated and reformulated, it is the fundamental principle of modern toxicology and the basis of the study of dose-response relationships.

Until relatively recently, the study of hazardous substances largely focussed on the acute, relatively immediate, and sometimes reversible effects of exposures. To assess potential health effects, experiments on animals were conducted at different exposures until an exposure was found at which no adverse effects were obvious. This no-observed-effect-level (NOEL) was in turn divided by a safety factor to achieve a "safe" level of exposure for man. Implicit in this approach was the assumption of a threshold in the dose-response relationship, while the "safe" level was a form of de minimis level.

With technological improvements and the rising profile of risk assessment in health protection, the conventional (NOEL) approach to toxicology came to be regarded as inadequate especially for evaluating non-threshold, chronic effects of low exposures, and specifically the behaviour of carcinogens and mutagens. To overcome this inadequacy, the response component of dose-response curves is transformed into the risk of occurrence. The dose-risk relationship is then extrapolated to a sufficiently small "virtually safe dose" (VSD). The annual risk of fatality for an individual at which a dose is assumed to be "virtually safe" is often in the range of 10^{-6} to 10^{-8}. The similarities between a VSD and a de minimis level are obvious.

In recent years, the study of carcinogenesis and other aspects of toxicology has become a major component of health protection efforts in many countries. Two major causes of this trend are the discovery and/or suspicion of increasing numbers of carcinogens in the environment and a public disposition to allocate resources to cancer research. While much is being learned, it is also true that there is much more to be learned and that discoveries can disrupt previous theories and beliefs. As a result, several aspects of toxicology currently are

undergoing vigorous debate. A sampling of these include:

- the growing recognition that people are exposed to naturally-occurring carcinogens in virtually all foods, water and air;
- the possibility that the relationship between exposure to certain substances and the occurrence of cancers may demonstrate thresholds;
- the questioned appropriateness of various dose-response models currently in use; and
- the potential overextension of toxicology by the desire or need to regulate.

That nature is not as benign as was once thought is becoming apparent as carcinogens are discovered in many plants and animals, known to be created by routine metabolic processes, and produced by natural events such as volcanic activity. For example, human dietary intake of naturally-occurring, carcinogenic pesticides is estimated to be about ten-thousand times that of synthetic pesticides, yet little is known about the toxicology of most plant toxins (Ames, 1983).

Various researchers have recently proposed that certain chemicals that are associated with the development of cancer may have thresholds. This is based on the speculation that such agents are active only at high sustained doses and, up to a certain point, the effects they induce are reversible (Perera, 1984). Thus, it may be possible to formulate safe levels of exposure after appropriate (long-term bioassay) toxicologic dose-response studies are conducted (Weisburger and Williams, 1981). This suggestion has come under strong attack on the basis that not enough is known about the mechanism of carcinogenicity or genotoxicity to support such a threshold hypothesis. On the other hand, some researchers have supported the pursuit of

evidence relating to carcinogenic thresholds (Squire, 1984).

Some of the criticisms of the commonly used low-dose extrapolation models are reviewed in Section 3.2. In general, the mathematical models attempt to predict the number of test animals that will respond or show effects at low levels of exposure. The models reveal little about human response at any exposure level. The assessment of human response requires judgements based on broad biological assumptions, or comparative metabolic data if any are available, and must to some extent be arbitrary.

These and other frailties of the data have led some toxicologists to warn that the science is being pushed beyond its limits to the increasing disadvantage of society (Hall, 1984). In a similar vein, others see the biologist, the chemist and the statistician all working far beyond the region of reliable science (Horwitz, 1984). The net result is that "we use bad math and arbitrary legislation to cover missing biology" and at the same time "we use statisticians and worse yet, lawyers, in place of biological scientists" (Hall, 1984).

Amid such debate over fundamental issues, it is not surprising that the de minimis concept per se has not yet received much attention from the disciplines that deal with the effects of exposure to non-radioactive substances.

2.4 Role in Radiation Protection

Recent publications from several radiation protection agencies suggest that the de minimis concept is most often presented or perceived either as the third component in the overall approach to regulating exposures, or as a way of truncating or limiting

the calculation of collective doses.

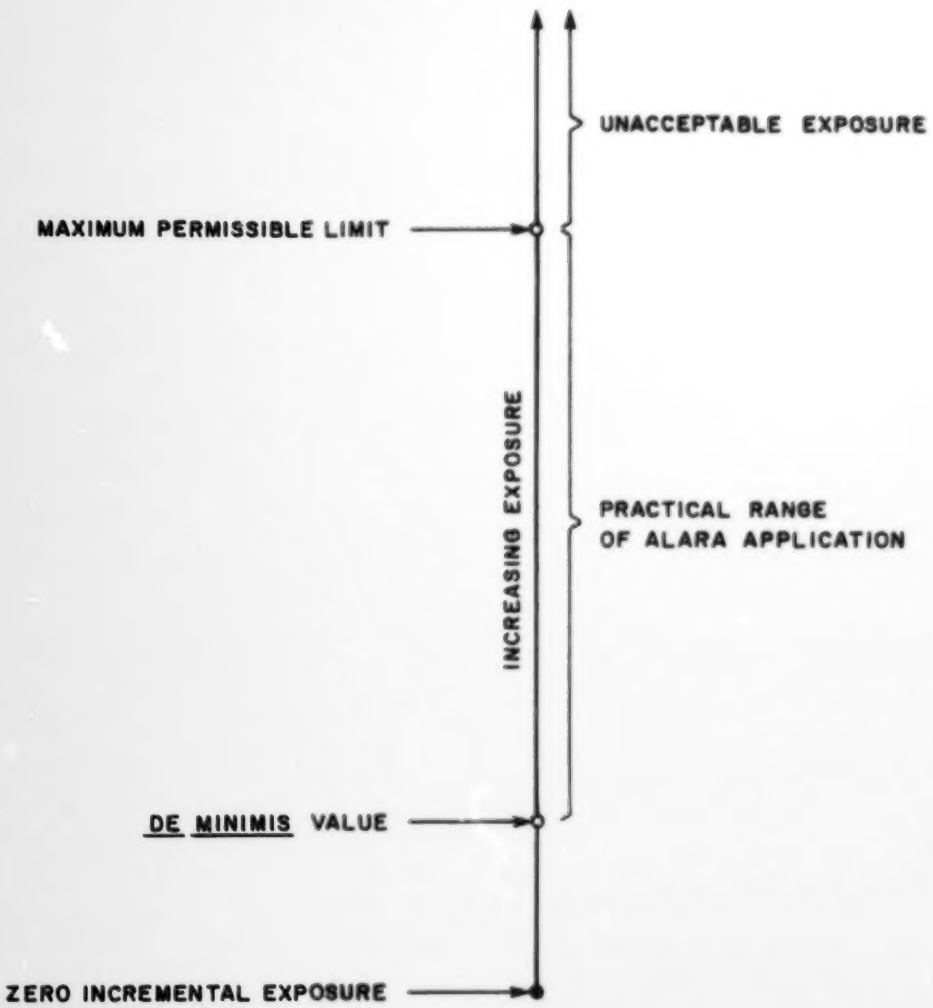
The first component in the overall approach to regulating exposures is the determination of a maximum permissible level. This usually is a legislated numerical value such as the 5 mSv/y limit for members of the Canadian public included in the Atomic Energy Control Act (1974). The second component is the principle (which has been adopted by many radiation protection agencies) that exposures should be reduced below the maximum permissible to levels as low as reasonably achievable, taking into account social and economic considerations (also referred to as the ALARA principle). The third component is a de minimis level, below which further efforts of dose reduction need not be considered under any circumstances (Cunningham, 1983; Meinhold, 1984; OECD/NEA, 1984; Davis, 1984; Guimond and Galpin, 1984). The relationship between the three components is illustrated in Figure 2.1.

As the third component, the de minimis level represents a practical end point or "floor" for the range of application of ALARA analysis. It is important to note that a de minimis level should not be perceived to be the ultimate goal of exposure reduction (that is the objective of an ALARA analysis) but rather should be used only to identify exposures that need not be considered further (Meinhold, 1984; Cunningham, 1983).

A second role for the de minimis concept is to identity limits for the sizes of populations or durations of time over which collective doses would need to be considered (Webb and McLean, 1977; Mills, 1983; Chatterjee et al., 1982; Davis, 1984; Meinhold, 1984). Supporters of this role argue that this would eliminate the integrations over space and time that have been used to predict large numbers of health effects (on a statistical basis), but which actually represent upper limits and reveal very

FIGURE 2·1

RELATIONSHIP BETWEEN COMPONENTS OF RADIATION EXPOSURE REGULATION AND EXPOSURE LEVEL



little about real situations other than that the actual effects lie somewhere between zero and the numbers calculated. Conversely, this use of the concept has been criticized as not taking into account potentially important components of the collective dose (see Section 3.6) and possibly ignoring several trivial exposures which could combine to produce non-trivial effects.

Some investigators have suggested de minimis values for only one role (as the third component in exposure control), others have presented different values for the two roles (exposure control and dose truncation), and yet others have suggested different values for various applications such as waste disposal practices, remedial action target limits, and for multiple source exposures (Davis, 1984).

The most frequently cited application of the de minimis concept is to identify radioactive materials that are exempt from disposal regulations. For this type of application, a de minimis value of annual dose is derived. Materials that could lead to exposures less than the de minimis value would be exempt from regulation. Some public utility and industry representatives have expressed support for this type of application (Sorber, 1984; Davis, 1984; Whipple, 1984).

Radiation protection agencies in Canada and the United States have used the essence of the de minimis concept by ruling that certain low level radioactive sources such as scintillation fluids and ionization-chamber smoke detectors can be placed in unlicensed waste disposal facilities. Guidelines have also recently been developed by the U.S. Nuclear Regulatory Commission for the submission of petitions seeking to establish de minimis levels for other types of low level waste material (Cunningham, 1983).

Similarly, there are criteria which identify when remedial measures should be instigated to reduce inadvertent radiation exposures. For example, remedial measures to reduce the levels of radon and radon daughter products in Canadian houses are recommended only where certain action levels are exceeded (AECB, 1977).

2.5 Current Trends

While it has been an underlying component of health protection and risk management for many years, the de minimis concept and the possibility of its explicit incorporation into legislation have increasingly been included in recent discussions and investigations. Several reasons have been suggested for the increased attention being directed to the de minimis concept and closely related aspects of risk regulation:

- Technology has developed to the extent that potential sources of very small risks can be identified or postulated; in fact, sources and estimated levels of risk can be identified that the general public has difficulty understanding.
- Society has already recognized and responded to most immediately obvious health risks that are commonly faced thus allowing attention to turn to smaller risks.
- Potential low level risks are now being discovered in many conditions previously thought to be benign. This is prompting a shift in perception from one of completely eliminating risks to one of learning to manage risks.
- Attempts to resolve differences over the control of very low levels of predicted risk are becoming costly, slow, inefficient and often unsatisfactory to all parties

involved. Regulatory agencies are increasingly being forced to take positions on unknown or incompletely understood hazards, industry complains about inconsistency and inequity in regulatory philosophy; the judiciaries hear cases that are cumbersome and immersed in uncertainty; and the public is confused by the nature of the arguments and the conflicting views of supposed experts.

These factors and others suggest that the need to resolve various issues surrounding the quantification and interpretation of small risks is growing in urgency. The de minimis concept may be able to contribute to the resolution of some of these issues and thus it merits consideration in the formulation and interpretation of legislation.

3.0 ADVANTAGES AND DISADVANTAGES OF THE DE MINIMIS CONCEPT

3.1 Some General Observations

Two commonly encountered sentiments about the incorporation of the de minimis concept into legislation are its desirability (some even assert necessity) and the difficulties that such actions could present. Usually the advantages or benefits are listed in a few points and there appears to be general agreement as to what these are. On the other hand, the disadvantages or undesirable aspects appear to be many and varied. As a result, relatively large portions of the following sections address the disadvantages. This should not be interpreted from the outset as meaning that the disadvantages associated with the concept outweigh the advantages.

The prime advantage often attributed to the de minimis concept is that it can prevent the spending of society's resources (which are finite) on insignificant matters to the detriment of those more deserving. This advantage is based on ethical and economic grounds. Technical and administrative considerations also support it.

The technical consideration is the relief the concept can provide to the assessment of effects so small or improbable that the uncertainty inherent in the assessment techniques being used makes estimates of the results unreliable. Similarly, the administrative aspect stems from the belief that the application of the concept will rationalize the regulatory process by making it more consistent, cost effective, equitable and predictable (Davis, 1984).

3.2 Health Protection Philosophy

Despite the fact that the essence of the de minimis concept is implicitly part of many regulations, it does not appear to fit cleanly into current health protection philosophy. More importantly, it appears that before it can fit explicitly, considerable change will be needed in the attitudes of society and its regulators.

A major component of the assessment of human health effects resulting from exposures to most substances is the laboratory study of human surrogates (i.e. test animals) that receive relatively high rates of exposure. This makes it necessary to extrapolate from the observations of the test animals to humans, and to extrapolate from test exposure levels to those that are more likely to occur. Often the actual exposures are several orders of magnitude lower than the laboratory exposures.

There is general agreement that the methods used for extrapolation have many limitations and that the results must be interpreted with caution. Generally, the results of extrapolation become increasingly weak as the exposures being evaluated become farther removed from the conditions actually studied. This has prompted some critics to accuse extrapolation of being statistically invalid for estimating low exposure health effects (Eichholz, 1980), while others have felt so strongly as to call such extrapolation scientific malpractice (Hickey, 1984). Nevertheless, extrapolation remains a vital technique in toxicology and numerous mathematical models have been created for this purpose.

Most of the extrapolation models are based on the assumption that health risks cease to be present only when exposure does not occur. The premise that there is some risk regardless of how

small the exposure is often referred to as the no-threshold hypothesis. This has become one of the key components in the regulatory philosophy of health protection. It initially gained acceptance in large part through applications concerning the effects of radiation exposure (Pochin, 1978b).

Whether the no-threshold hypothesis accurately represents the dose-response relationship at very low doses of any substance has been a matter of speculation and debate for many years. Even when considering the effects of radiation exposure (for which data are relatively abundant and available for relatively low exposures), it appears that the "true" shape of the dose-effect curve will never be known (U.S. National Academy of Science, 1979; Efron, 1984). Given that such unknowns exist and appear difficult (if not impossible) to resolve, the no-threshold hypothesis has often been advocated as being a prudent and conservative (and thereby desirable) component of health protection.

Extrapolation models are used to predict relationships between exposure and risk. To establish regulatory or legislative objectives, those parts of the models where annual risks of fatality range from 10^{-5} to 10^{-8} are often considered. Whenever a specific exposure is designated in legislation as "safe", "acceptable", or "tolerable", a de minimis type of decision has implicitly been made.

Several aspects of health protection philosophy are related to the no-threshold hypothesis. For example, some health protection agencies subscribe to the view that exposure to the smallest health insult (such as one molecule of a substance or one unit of radiation) may trigger an adverse, irreversible health effect (such as a cancer), or that it is necessary to strive to protect even the most sensitive individual in a population. These types of sentiments often play prominent roles in the philosophies

presented by agencies to the public. Often portrayed as being morally proper and necessary, they influence and sometimes distort public expectations of the level of health protection provided. Absent from either view is the notion of risk, the inability to completely eradicate risk, the practical need to accept some level of risk, and the different relative reductions of risk obtainable from alternative expenditures of resources.

Adoption of the de minimis concept would require the public and regulators to modify these perceptions of health protection. Some might argue that this is nothing more than a call for a more pragmatic, realistic approach, while opponents could argue that adoption of the de minimis concept represents a possible reduction in health protection for all members of the population in general, and hypersensitive individuals in particular.

Prior to explicitly incorporating the de minimis concept into regulations, these types of differences in attitudes would need to be resolved. Calls to change the objectives, philosophy, methodology or even public ideology of health protection might well meet with considerable resistance.

Should the de minimis concept become widely accepted by society as meriting explicit inclusion in regulations, many existing regulations could be affected. The explicit incorporation of the de minimis concept into any code of practice (such as that for uranium tailings management) could subsequently draw attention to the implicit de minimis values found in other pieces of legislation. Investigation would most likely reveal that the implicit de minimis values are inconsistent in the degrees of health protection they offer. In turn, this could lead to calls to re-establish all the de minimis levels (implicit and explicit) using a consistent methodology and generating a consistent level of protection. While beneficial in the long run, the process of

achieving this consistency could be traumatic.

That inconsistencies exist in the degrees of health protection offered by various regulations is not unexpected. One factor contributing to such inconsistencies is the societal attitude (and associated commitment from regulators) to resist technological changes that appear to introduce "new" risks or hazards. That these are not new risks but rather replacements for existing risks is often overlooked (Pochin, 1984; Huber, 1984). Another factor is that it is easier for regulators to impose stricter demands on proposed facilities than to bring about changes in existing practices. Thirdly, society is more tolerant of risks associated with established practices than those of new technology which threaten to undermine the perceived safety of the status quo (Huber, 1984).

Such attitudes are not without disadvantages. Lost opportunity costs are not always zero. Furthermore, it has been argued that the economic well-being of a society or country and the general level of health it experiences are directly related and that a decline in the economic well-being eventually will lead to a decline in the level of health (Wildavsky, 1980). Taken to the extreme, such attitudes could divert the scientific process from strengthening an economy to threatening or paralyzing it (Lave, 1984). While intending to protect itself, a society that too sharply inhibits technological progress may actually be doing so to its own detriment.

3.3 Administration

Potential administrative difficulties associated with the de minimis concept can involve conflicts with existing legislation, the different interests of local and national regulatory

agencies, and issues of practicality.

As noted in Section 3.2, establishing de minimis levels for uranium tailings could turn attention to the existing inequities in the extents to which different industries are regulated. Most likely, the long-established, "older" industries would be found to be less stringently regulated. Such inequities could be used to cast doubts on administrative objectives and practices.

The de minimis concept can conflict with any legislation not sensitive to risk considerations. For example, "best available technology" types of legislation depend on the capabilities of control technology. Other "absolute" types of legislation (i.e. those that forbid the use, transport or disposal of "any" radioactive material under certain scenarios) would be contradicted by the de minimis concept. (Indeed, by being so resolute, compliance with such legislation is impossible anyway.) Furthermore, some existing legislation may have no provision to allow for amending by an exemption concept.

For a health protection agency, the doses to the individuals in the group or community that it serves are its first concern. The analysis of exposures down to de minimis levels however, might often extend beyond the populations located within the jurisdiction or interests of local health protection agencies. Subsequently, a national agency might evaluate regional or national populations in assessing practices and arrive at opinions of practice desirability that differ from those of the local agency. Extended further, a national agency might choose to neglect detriment in other countries.

If a national protection agency did adopt the de minimis concept, local agencies might not choose to honour or accept it. Recent

experience in the U.S. which allowed certain radioactive materials to be disposed with other wastes incurred local resistance as well as administrative and practical difficulties in segregating exempt waste material from non-exempt material (Guimond and Galpin, 1984).

Concerns of practicality have prompted the U.S. EPA to urge that any legislation incorporating the de minimis concept must be compatible with existing management systems and the capabilities of radiation measuring instruments (Guimond and Galpin, 1984). If risk was chosen as the basis for establishing de minimis levels (see Appendix C), and if a consensus could be reached within an agency as to the value of an insignificant or trivial level of risk, would the same risk value be suitable or applicable to assessment of non-radioactive substances such as metals or pesticides?

As a topic that would attract considerable scrutiny, any agency's formal position of de minimis would have to be well-reasoned and comprehensive. Furthermore, the positions of all agencies within the government would have to be seen as being consistent with the same basic philosophy.

Prior to its explicit adoption, the de minimis concept should be shown as providing a net benefit. Creating new legislation that merely adds to the costs, confusion, or administrative bureaucracy would defeat one of the principal objectives of pursuing the de minimis concept.

3.4 Economics

The de minimis concept, or a variant of it, is implicitly employed in cost-benefit analysis in economics. In principle,

the decision rule is based upon a notion of the benefit/cost ratio exceeding unity for a project or program to be considered viable. Thus the ratio itself is a form of de minimis since it comprises a minimum value upon which decisions may focus.

Individuals regularly use a modified, unstructured form of cost-benefit or risk-benefit analysis. Deciding to drive faster than the speed limit to reach a destination sooner, enjoying a cigarette, or foregoing a check-up at the dentist all imply that some sort of cost-benefit analysis has been made. Because the personal resources of each individual are finite, decisions are constantly required of each of us to optimize their use and maximize each person's "quality of life".

On a broader scale, groups of individuals (usually as government bodies) also use cost-benefit analysis to help decide courses of action and resource allotment. In recent years, cost-benefit (risk-benefit) analysis has been increasingly proposed as a method of assisting decision-makers. While the philosophy of optimization is appealing, ALARA and similar concepts have proven to be difficult to apply in practice. These difficulties stem in part from weaknesses encountered in accurately quantifying the costs and benefits to both individuals and groups.

The application of the concept is an attempt to identify some social parameter specific to each program or regulatory proposal below which it should be unnecessary to conduct investigations or to regulate. Within this framework, cost-benefit analysis is part of the response when de minimis values are exceeded.

The underlying rationale is that cost-benefit analysis itself is part of the regulatory process. The analysis itself imposes resource burdens on regulators and upon those regulated. The de minimis concept would seek to determine if there is a point where

the expected benefit level is so low that there is not a prima facie basis for requiring a cost-benefit analysis. If such a decision rule could be established, it could guide both the regulator and the regulated and result in the elimination of wasteful and excessive analyses. The considerable problem facing such a study is how are the potential benefits of analyses to be estimated without conducting the investigation itself? For regulatory agencies to be secure in such practices, it would be necessary to develop a strong protocol for the methodology.

The de minimis concept appears to offer several opportunities for improving the effectiveness of health protection (or risk regulation). Three examples of potential economic benefits include the elimination of wasteful practices in handling, shipping and disposing of low-level waste materials; more effective use of special disposal repositories; and, relief to regulators from the monitoring, record keeping and assessment of trivial matters. The net result could be savings to the generators of de minimis materials and their shareholders, potential savings to their customers, the ability of regulators to shift resources to more pressing matters, and savings to the source of regulatory funding, the public.

3.5 Ethics

The de minimis concept concerns two major ethical issues:

- Is its adoption and use morally justified in some contexts, and if so, which?
- At what level, and chosen by what criteria, should a dose, risk, or concentration be treated as de minimis?

Many of the same considerations relevant to the philosophy, administration, and economic issues of health protection are also

relevant to the ethical issues. This is partly because a strong case can be made for stating that it can never be morally obligatory to waste resources. Below certain levels of risk, the benefits to be derived from further attention to certain conditions or concentrations are so minute relative to the costs, and the benefits attainable at that cost in other areas are so much greater for other applications, that expending resources on those conditions or concentrations would be wasteful regardless of the way potential benefits are defined. Often the costs even of investigating a substance would be greater than the maximum potential benefits derived from doing something about it. This and other considerations have supported the conclusion that adopting a de minimis concept is morally justified if correctly defined.

A number of related ethical issues alluded to in this report are not discussed in detail. These are mostly issues of distribution of one kind or another. One is the issue of who has moral standing or moral rights. To whom must a concentration or dose be trivial before it is accepted as de minimis? If only people have moral standing, is this limited to living people, or should future generations be included. Some animal rights groups advocate that other animals as well as man, should be considered. Should moral standing be expanded to include the entire ecosphere or biosphere?

Most studies of health effects are restricted to human populations. If there is a de minimis level applicable to people, it can be argued that a level applicable to the most biologically sensitive of living things is, for a stronger reason, sufficiently protective of other members of an ecosystem. The effects on non-human animals (let alone natural sites or ecosystems) are seldom considered. Although the restriction of health effects studies to human populations is a generally

accepted practice, it is recognized that some individuals argue against it.

Another issue is distributional fairness. As noted in Section 3.2, new technologies often must meet more stringent standards concerning risk of detriment than older technologies. From a moral point of view, this is difficult to justify. Similar distributional unfairness can be produced by the practice of setting individual risk limits. Many health protection laws and regulations attempt to reduce risks, often to specific individuals or small groups. Individual risk limits are appropriate in cases where individuals face relatively high risks. But when individual risks are not inequitably high and the motivation for risk management comes more from having a large number of people facing a low-to-moderate risk, rather than from having a few people at high risk, then individual risk approaches can produce resource misallocations (Whipple, 1984). This source of misallocation can be overcome by the use of different de minimis levels for individuals and large groups as illustrated in Chapter 4.0 and suggested by several agencies and researchers.

While few would argue with the idea of reducing risk, the de minimis concept reflects the idea that there is a limit to such reduction. That such a limit should exist has been advocated on the grounds that the greater the effort to reduce risks, the less equally is risk distributed among the population (Wildavsky, 1980).

There is a closely related distributional issue in reducing the risks to some people (often people who have already benefited from a technology) to levels that are lower in some cases than the risks from other factors to many of the people (often taxpayers) who are paying to reduce the aforementioned risks, and who may not have benefited or benefited so highly.

A full examination of these and similar distributional questions would have taken the study team much more deeply into the ethical foundations of the de minimis concept than the scope of this study allowed. Similarly, some other ethical issues of a somewhat more sophisticated nature have not been addressed such as how progressively lower risk levels can be shown to justify a decreasing obligation to lower them further, and at what point the obligation disappears altogether (Brook, 1983).

3.6 Some Technical Considerations

Potential technical difficulties associated with the de minimis concept involve the uncertainties in the mathematical models needed to estimate doses, the translation of risk to dose, and the conversion of dose to a directly measureable variable such as a concentration, quantity or release rate. Demonstrating that de minimis conditions exist will be a largely theoretical exercise relying heavily on mathematical models and statistical techniques. Given the relatively small doses being evaluated, the magnitudes of the exposures to be estimated may be overshadowed by the degree of uncertainty inherent in the techniques used to calculate them.

Currently there is no consensus on either the method or the appropriateness of ignoring de minimis levels of exposure in calculations of average individual dose or collective dose (OECD/NEA, 1984). Furthermore, there are uncertainties as to the implications the de minimis concept presents to the assessment of multiple sources even though each source may generate below de minimis exposures.

4.0 THE DE MINIMIS CONCEPT AND URANIUM TAILINGS MANAGEMENT

4.1 Study Definitions and Guidelines

Preceeding chapters are based largely on the work of others as interpreted by the study team. This chapter, however, is the product of the lessons learned in reviewing the literature and the experience and judgement of team members.

Despite the amount of literature reviewed by the team, or possibly because of it, it was deemed necessary to carefully consider and formalize the definitions of some key terms prior to addressing the possible role of the de minimis concept in uranium tailings management. Some definitions and clarifying notes therefore are presented below to assist readers' understanding of subsequent discussions in this chapter concerning the application of the de minimis concept to uranium tailings management. These definitions are not all-inclusive nor necessarily acceptable for other purposes.

Harm or harmful effects include probabilistic effects (such as cancer) and threshold effects (such as eye cataracts) both of which are sometimes called "objective" health effects. It also includes the concern and anxiety of the individuals at risk.

Risk is the probability of occurrence of a particular harmful effect. For example, the risk associated with a given dose (from radiation or otherwise) is the probability that an individual will incur an induced health effect as a result of the dose received.

Detriment is the total harm calculated from the integration of risk over all space and time. This is normally quantified only

for objective health detriments (for example, cancer or morbidity) although other effects (such as psychological anxiety and economic losses) can be included, at least conceptually, in the total detriment.

A linear, dose-effect relationship is currently used to evaluate the potential radiological detriment arising from radiation exposure (see Section 3.2). Similar practices are also applied to other, non-radioactive agents that are known or suspected carcinogens. Thus, in principle, any dose, no matter how small, represents a risk. Although a very small dose may carry an attendant risk which is truly trivial, such doses and risks can be calculated (at least in principle) and incorporated into the evaluations of dose (or risk) such as those that might be used in a cost-benefit or ALARA type of analysis. The conservative nature of the linear, dose-response relationship at the very low doses implied in discussions of de minimis is an important consideration. If, for example, it could be demonstrated that a threshold dose exists, then all doses below the threshold would truly be de minimis and no risk would accrue at those doses. If a threshold cannot be identified, the integration of dose or risk nevertheless can (must) be **truncated** either in space or in time. For example, the incremental radon exposures resulting from a uranium tailings pile might be calculated to a distance of 50 km from the pile ("truncation in space") or up to 1000 years into the future ("truncation in time"). Such truncation results in what is sometimes called the "incomplete collective dose assessment".

Justification involves ethical considerations. The justification of a particular practice is taken to mean generally that all the merits and the harm associated with the practice and those associated with the possible alternatives to the practice are considered in reaching a decision on that practice.

Finally, the term **de minimis** must be defined. As demonstrated in the other chapters, de minimis has been presented in a number ot guises according to the various proposed methods of application. In somewhat generic terms, possible de minimis definitions include:

- a threshold in a dose-response relationship, or the no-observed effect level (NOEL);
- being insignificant by any reasonable standard;
- being insignificant within a certain time frame (for example, when the latency period of a cancer due to a particular exposure exceeds the lifetime of the person exposed);
- being insignificant relative to some cost (for example, the cost of an investigation to determine the effects of an exposure is greater than the cost (harm) resulting from that exposure); and,
- being insignificant relative to background exposure or risk. (No material including uranium tailings is totally devoid of radioactivity or other potentially harmful substances, such as arsenic or nickel; at some point in time or space incremental levels of exposure originating from a tailings area become so small as to be indistinguishable from the naturally-occurring exposures and the incremental risks can not be distinguished from the risks which would naturally exist in the total absence of the exposure originating from the tailings.)

The team chose to use all of these ideas in its definition of de minimis by concluding that the concept is needed only where a threshold does not exist or cannot be identified (since a true threshold establishes a true de minimis level), and that the last four ideas identify a minimum level to which exposures could

ideally be reduced; in other words, de minimis can be used to establish a practical floor for the range of application of an ALARA analysis.

Based on these characteristics, two possible general applications of the de minimis concept to the management of uranium tailings were identified by the team:

- to evaluate specific management practices by comparing the expected dose of the critical receptor to the de minimis value (if the latter value is greater than the receptor's dose, no further health protection effort is needed); and,
- to truncate calculations of dose or risk in time and space.

Both of these applications place limits on the efforts used in ALARA-type calculations.

4.2 Evaluation of Practices on the Basis of Individual Dose

The use of the de minimis concept in evaluations of individual doses or exposures provides, at least conceptually, a technique for avoiding undue effort on reducing or controlling very small risks arising from a particular practice or activity. With regard to uranium mill tailings, the de minimis concept might be used to define the region of dose (or risk) in which it is appropriate to carry out ALARA-type analyses to see whether or not there would be a net benefit in expending further resources to reduce dose or risk. The practical range of application of ALARA could then be considered as the region bounded above by the maximum permitted dose (risk) to an individual member of the public and bounded below by a dose (risk) which can be considered de minimis. If the maximum individual dose were predicted to lie below the de minimis level, then no further consideration of

dose reduction would be required.

The application of this concept becomes somewhat less clear however, when either the uncertainties in dose (risk) estimation are recognized or the added complexity from multiple sources is considered.

4.3 Truncation of Collective Dose

ALARA-type analysis usually involves the estimation of collective dose or risk. Both conceptual and practical difficulties arise in determining the spatial and temporal limits for the calculation of collective dose. The resultant collective doses often indicate large numbers of potential cancers or genetic effects, but they actually represent upper limits and reveal very little about the real situations, other than that the actual effects lie somewhere between zero and the numbers calculated. Such an approach may distort rather than help the decision-making practice.

Such integrations do not affect the estimated value of risk to an individual. Moreover, they cannot be used to illustrate the risks to society without a frame of reference such as the total number of people who lived and died in the area and time period of interest. Often the number of effects (e.g. cancer cases) calculated by such an exercise is dwarfed by the number of naturally-occurring cancers during the same period.

In view of such considerations, it may be appropriate to remember that the purpose of ALARA (and other types of optimization analysis) is to identify the preferred option or practice (in this case, it could be a method of tailings management that most effectively reduces dose). In other words, such an analysis

provides a basis for comparing different options in terms of the net effect. This is an important observation. For example, consider two options (A and B) for closing a tailings area. If after some point in time, the effect of the different close-out options can no longer be distinguished, there would be little point in predicting collective doses beyond that time. To illustrate this, let CDA(t) be the annual collective dose predicted to accrue if option A were implemented and CDB(t) be the annual collective dose predicted to accrue if option B were implemented. If after some time, t_f, the annual incremental doses from options A and B were not distinguishable, then

$$\text{difference in collective dose to infinite time} = \int_0^\infty CDA(t)\,dt - \int_0^\infty CDB(t)\,dt$$

$$= \int_0^{t_f} CDA(t)dt - \int_0^{t_f} CDB(t)\,dt$$

$$= \text{difference in collective dose to time } t_f$$

Similarly, if at some distance from the tailings area, it were not possible to distinguish between the collective doses for close-out options and the collective dose evaluations are to be used to compare options, then integration to larger distances would be neither necessary nor desirable. The dose truncation levels at which these occur are types of de minimis levels.

The identification of such truncation levels is not simple. The evaluator must recognize the uncertain nature of the calculations and a plethora of scientific and philosophical issues such as those discussed previously in this report.

However, notwithstanding other potential applications of ALARA (optimization), the use of de minimis values of dose (or risk) seem to provide one logical approach to truncating collective dose (risk) calculations in time and space.

4.4 Application Summary

As suggested by the foregoing, the potential application of the de minimis concept to uranium tailings takes two forms:

- as an aid to deciding if a specific practice or activity requires further investigation of dose and possible dose reduction efforts; and,
- in assisting to define limits in space or time for truncating the integration of collective dose.

The specific identification of numeric values for de minimis is beyond the scope of this study; however, Appendix C presents a brief survey of published de minimis values.

In view of the above, one possible way in which the de minimis concept could be applied to uranium tailings management is as follows:

- de minimis levels of risk would be defined for individual dose and for truncating collective dose estimates, the former being the greater of the two since the possibility of exposure to more than one source would be greater for a group than for an individual;
- both de minimis risk levels would be translated to exposures or doses;
- to evaluate a specific practice, all pertinent pathways would be analyzed for the critical receptor and if the

exposures were less than the de minimis exposure for the individual, no further effort would be needed for exposure reduction;

- if pathways analysis indicated that exposures greater than the individual de minimis level could be anticipated, the second de minimis value would be used to identify the appropriate point of truncation in time or space for estimates of collective dose.

This process could be applied in principle to either radioactive or non-radioactive releases.

The defining of de minimis quantities of materials may be somewhat more difficult than defining de minimis levels of risks or dose. Key to the establishment of the truncation dose would be the assumption that any individual was being exposed to less than a specific number of sources. In such a cose, the truncation dose could be defined as the individual de minimis dose divided by the specified number of sources.

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APPENDIX A STUDY TEAM MEMBERS AND CONTACTS

A.1 Team Members

J.W. Adams	Legal Counsel, Fraser & Beatty
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L.M. Lowe	Environmental Physicist, SENES Consultants Limited
M.N. Maxey	Professor Biomedical Engineering Program, College of Engineering, University of Texas at Austin
G.G. Stewart	Medical Doctor specializing in radiation health effects, private consultant
R.F. Willes	Toxicologist, F.D.C. Consultants Inc.

A.2 Others Contacted During the Study

R.J. Guimond	Director, Criteria and Standards Division (ANR-460), Office of Radiation Protection, U.S. Environmental Protection Agency, through correspondence in October 1984.
D.J. Martin	Atomic Energy Control Board of Canada, through conversations in December 1984.

C. Meinhold	Head, Safety and Environmental Protection Division, Brookhaven National Laboratory, through conversations in December 1984.
W.A. Mills	Health Effects Branch, U.S. Nuclear Regulatory Commission, through conversations and correspondence in December 1984.
J. Muller	former Chief, Health Studies Service, Ontario Ministry of Labour (retired), through conversations in December 1984, workshop participation in January 1985, and draft review in February 1985.
K. Wagstaff	Atomic Energy Control Board of Canada through conversations in December 1984.
C. Whipple	Technical Manager, Energy Study Center, Electric Power Research Institute, through correspondence in October 1984.

APPENDIX B POSITIONS OF VARIOUS AGENCIES CONCERNING THE *DE MINIMIS* CONCEPT

B.1 General Caveat

The following sections address only those agencies that have explicitly cited the *de minimis* concept or similar terminology in recent documents. While many agencies have endorsed the essence of the *de minimis* concept, it has not yet been explicitly incorporated into legislation. As a result, agency positions, and the form and function of the concept, must be regarded as preliminary and could undergo considerable changes from their current status.

B.2 Atomic Energy Control Board (AECB)

Staff of the AECB have proposed using the *de minimis* concept to identify radioactive materials that would be exempt from regulation (Chatterjee *et al.*, 1982). Risk was selected as the appropriate basis for establishing "trivial dose criteria". A risk of fatality of 10^{-7} per year and the corresponding annual dose was chosen as the level below which individual doses may be neglected. Based on the linear dose-risk relationship used by the ICRP, this risk translates into an annual individual effective dose of 10 uSv. For large populations (which the AECB has defined as more than 100,000 persons), any individual doses below 1 uSv could be ignored in calculating collective dose.

B.3 U.S. Environmental Protection Agency (EPA)

The EPA currently favours the terminology "Below Regulatory Concern" (BRC) to avoid potentially fostering a public perception of a non-caring attitude that the term *de minimis* might inadvertently impart (Guimond and Galpin, 1984). While a

BRC level has yet to be identified, preliminary investigations by the EPA have revealed both desirable and undesirable aspects of the concept and its possible application.

The EPA has discounted the possibility of using either risk or natural background radiation as the sole basis for setting BRC levels. Both present administrative difficulties within EPA and externally with other pieces of legislation. Using background levels also presents EPA with philosophical difficulties since the existence of exposures from natural sources is not seen by the EPA as justification for man-made exposures.

The EPA is now pursuing an inverted, cost-effectiveness analysis in which the benefits and risks involved in various levels of non-control are being evaluated. While leaning towards a BRC level in the form of an annual individual exposure, the EPA has not eliminated concentrations, specific activities, or defined mixtures of radionuclides as possible candidates. The EPA expects controversy in its efforts to develop BRC criteria.

Unlike other specific agencies mentioned in this chapter, the EPA is also responsible for regulating non-radioactive substances. Since a de minimis level of risk for one contaminant could be applied to others, various EPA departments presumably would need to come to an agreement on such a level of risk before a precedent is set. Being a large organization, this is not easily achieved. For example, while the Office of Radiation Programs has chosen to avoid the term de minimis, the Air Quality Planning and Standards Office has sponsored several investigative studies to develop explicit de minimis values for air pollutants (see U.S. EPA, 1980).

B.4 U.S. Nuclear Regulatory Commission (NRC)

The NRC opinion that a de minimis dose rate potentially offers several advantages is evident in its proposed changes to the basic radiation protection standards contained in 10 CFR Part 20 (Mills, 1983). As stated in its draft proposed rule, the Commission perceives de minimis as a level of risk (or dose) so low that it would be a trifle in comparison to the risks which the individual is subjected to daily as part of normal living habits and activities. It would constitute a level of risk so low that no resources could be justified to control it, or to be further concerned with it (Cunningham, 1983).

Based on the Commission's policy to use quantified risk as an important factor in decision making, an acceptable lifetime risk of one-in-a-million has been identified. Considering factors relating to dispersion, bioavailability, lifetime of a facility and others, a value of 10 uSv/y would be used for exposures to individuals from an NRC licensed source. To account for dose contributions from multiple sources, a 1 uSv/y de minimis value would be used for consideration of population doses.

The de minimis level would be a regulatory cutoff applicable to any NRC licensed activity. Prior to formalizing its position concerning de minimis, the NRC will take into consideration the recommendations of the National Council on Radiation Protection and Measurements (NCRP) and guidance from the EPA. Like the EPA, the NRC has raised the concern that doses greater than de minimis may be seen by the public as being unacceptable or dangerous (Cunningham, 1983).

B.5 U.S. National Council on Radiation Protection and Measurements (NCRP)

It is anticipated that the NCRP will be issuing the findings of an extensive evaluation of the de minimis concept in 1985. In the interim, it has been reported that the NCRP will advocate that risk be the basis for determining de minimis levels (Meinhold, 1984). The likely "negligible risk level" (the preferred NCRP terminology) will be an annual risk of 10^{-7}, which corresponds to 1 mrad/y (0.01 mGy/y) of low linear-energy-transfer radiation. Unlike the ICRP, the NCRP will advocate using the negligible risk level as the truncation point in the calculation of population doses.

B.6 International Atomic Energy Agency (IAEA)

The IAEA has used the de minimis concept in its recommendations concerning the disposal of radioactive material in the terrestrial environment (Dlouhy, 1981) and at sea (IAEA, 1981). Prior to 1981, the IAEA had recommended concentrations and quantities for several specific radionuclides. That approach subsequently was seen as inadequate and it was recommended that a de minimis level of exposure be determined based on risk or natural background radiation considerations and that the resulting value be converted to concentrations or quantities of radionuclides in waste materials.

Based upon the decision that 10^{-7} is an acceptable annual level of risk, the IAEA has recommended a de minimis value of 10 uSv/y for the average individual in a critical group. Furthermore, it has recommended that any single nation should not discharge materials to a single ocean basin that result in exposures of more than 1 uSv/y. This would minimize the possiblity of exceeding the 10 uSv/y level in the event of

several nations discharging to the same ocean basin. The IAEA recognizes that the dose values need to be converted to concentrations or release rates but is uncertain how this should be done.

B.7 International Commission on Radiological Protection (ICRP)

The ICRP, an agency that influences radiation protection efforts in many countries, has not recommended the use of the de minimis concept. In a discussion of a practical lower limit in the determination of collective dose however, the ICRP has noted that "... at low levels of individual dose, e.g. those small by comparison with variations in local natural background, the risk to the individual is so small that his health and welfare will not be significantly changed by the presence or absence of the radiation" and that "... at levels of individual dose that are small fractions of the relevant dose limit, there will be no need to pursue the summation beyond the point where it becomes clear that the further contribution to the sum will not change the estimate of population dose by more than a factor of 2 or 3..." (ICRP, 1973).

The ICRP has recommended that the time span to be considered in calculating collective doses should extend until the similarities or uncertainties in collective dose rates no longer allow alternatives to be distinguished. This time span is case-specific and cannot be selected prior to analysis.

B.8 Organisation for Economic Co-operation and Development Nuclear Energy Agency (OECD/NEA)

The OECD is another agency that perceives the de minimis concept as providing a "floor" for the optimization of risk-benefit analysis; in other words, it identifies exposures that need not

be reduced. While the OECD recognizes the theory that below certain levels (maybe 10^{-7} to 10^{-8} per year) risks are insignificant to individuals, it notes that there is no consensus that the collective doses associated with such exposure may be ignored (OECD/NEA, 1984). Furthermore, truncation of low individual doses from collective dose calculations will favour practices involving widespread dispersion and exposure to a large population. In these cases, a significant part of the collective detriment could occur outside the borders of the country authorizing the practice.

B.9 Other Agencies

Just as the de minimis concept is seldom mentioned in the literature for non-radioactive substances, so too it is a subject not often broached by agencies that regulate such substances. Should the de minimis concept become an explicit part of radiation health protection, these other agencies might experience increased pressure to investigate the incorporation of the concept into other health protection codes of practice.

APPENDIX C SOME SUGGESTED APPROACHES TO QUANTIFYING *DE MINIMIS*

C.1 General Categories

Many researchers have addressed the concept of *de minimis* and have proposed several approaches to determining *de minimis* levels of exposure, particularly to ionizing radiation. The different approaches can be classified into three general categories based upon the philosophy and evidence used in their support: risk, natural background exposure, and biological effects. Each of these categories is briefly discussed below. Figure C.1 displays some of the *de minimis* values that have been proposed for radiation exposure.

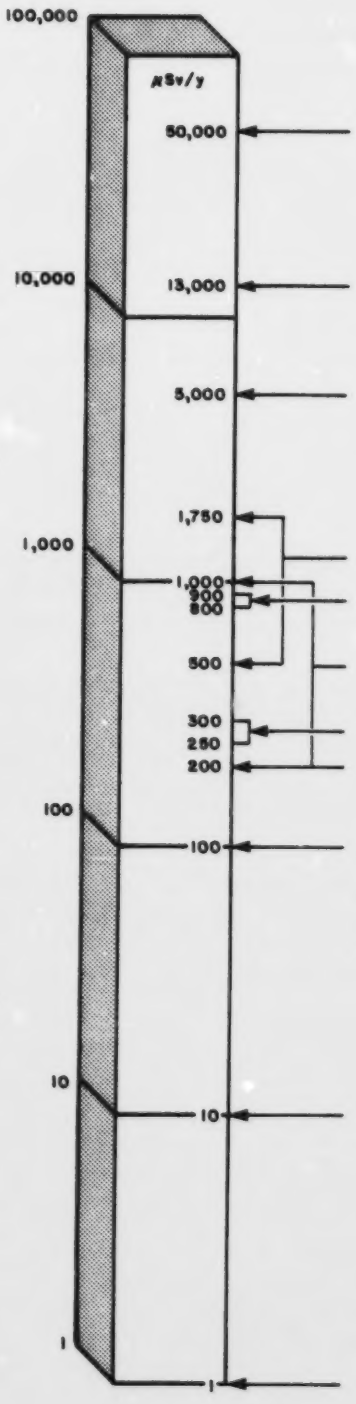
C.2 Risk

As noted in Chapter 2.0, all activities entail some risk. While there is no conclusive evidence that low doses of radiation result in health detriment, it is generally assumed that there is some risk associated with any exposure no matter how small (ICRP, 1977). These risks can be estimated and compared with the risks of other activities. The risks of small-dose, low-dose-rate exposures are customarily expressed as the lifetime chance that a detrimental effect, such as cancer, will be caused by an increment of dose. That this is a calculation of a probability must be emphasized, since the potential effects would occur only randomly among an exposed population. At sufficiently small probabilities, such risks no longer influence the behaviour of an individual and can be designated as "trivial" and thus identify a *de minimis* level.

As analyzed by the International Commission for Radiological Protection (ICRP) and other recognized scientific organizations, the risk of death (primarily from cancer) is approximately

FIGURE C·1

SUMMARY OF SUGGESTED DE MINIMIS LEVELS AND SELECTED LOW LEVEL RADIATION EXPOSURES



NOTE:
ALL VALUES ARE FOR EXTERNAL RADIATION EXCEPT THE MAXIMUM PERMISSIBLE EXPOSURE WHICH ALSO INCLUDE INTERNAL EXPOSURES.

50,000 — MAXIMUM PERMISSIBLE EXPOSURE FOR ATOMIC RADIATION WORKERS.

13,000 — NATURAL BACKGROUND AT KERALA AND MADRA STATES, INDIA.

5,000 — NATURAL BACKGROUND AT COASTAL AREAS OF BRAZIL. MAXIMUM PERMISSIBLE EXPOSURE (BEYOND NATURAL BACKGROUND) FOR MEMBERS OF THE PUBLIC IN CANADA.

1,750 — RANGE OF BACKGROUND EXPOSURE COMMONLY ENCOUNTERED IN NORTH AMERICA.

1,000
900
800 — WORLD CALCULATED AVERAGE NATURAL BACKGROUND.

500 — DE MINIMIS RANGE RECOMMENDED BY EISENBUD, 1980.

300 — DE MINIMIS INFERRED FROM WORK OF ROSSI, 1980.

250
200 — STANDARD DEVIATION OF NATURAL BACKGROUND IN U.S.

100 — DE MINIMIS RECOMENDED BY WEBB AND McLEAN, 1977.
EXPOSURE WITH ONE-IN-A-MILLION CHANCE OF FATALITY

10 — DE MINIMIS SUGGESTED BY AECB (CHATTERJEE et al, 1982) AND US NRC (CUNNINGHAM, 1982).

1 — DOSE TRUNCATION POINT FOR LARGE POPULATIONS (CHATTERJEE et al, 1982).

one-in-ten-thousand for a radiation dose of 10 mSv to the whole body. From that estimate, the linear hypothesis indicates that an exposure of 100 uSv presents a one-in-a-million risk of death to the exposed individual. The same dose to limited portions of the body produces smaller risks. This value has been proposed as a suitable de minimis level for exposure to individuals (Webb and McLean, 1977). If the risks of genetic effects are also considered, the ICRP estimates that the one-in-a-million risk is approximately 50 uSv.

It has also been suggested that for population groups, an average risk of 10^{-5} per individual be acceptable and estimates of dose that differ from zero by less than one-tenth of the standard deviation of the dose estimate be considered to be "identically zero" (Eichholz, 1980). An "identically zero" probability per individual would then represent a zero risk to a larger population regardless of size. Further study would be needed to refine this suggestion and to select a specific numerical value if it were to be used in population risk estimates.

C.3 Natural Background Exposure

Life on earth has evolved in an environment that provides continuous exposure to chemical substances and ionizing radiation. Relatively small amounts of many of the chemical substances that society tries to control are found in food, water, and air. Others are created by the ways we use fuel, prepare meals, or choose to live. Yet others are produced by various bodily functions (Ames, 1983).

"Background radiation" originates from cosmic and terrestrial sources and varies widely with location. Attempts to correlate health detriment with variations in background exposures have

generally been unsuccessful, although some correlations, positive and negative, have been reported. This has prompted the premise from some scientists that exposures that are "small" in comparison to the inescapable background levels present insignificant risks.

Several methods have been suggested for deriving a de minimis level for radiation based on background levels. One approach proposes that doses of the order of geographical variations in natural background should be considered to be de minimis (Eisenbud, 1980). In Canada, individual doses from all natural sources typically lie in the range of 1000 to 2000 uSv/y with variations within any geographic region varying by 100 to 200 uSv/y. This method suggests a de minimis level in the range of 100 to 200 uSv/y.

A related approach uses the standard deviation of the background exposure rate, weighted with the exposed population (Adler and Weinberg, 1978). Analysis of background radiation exposure data for the United States indicates that the standard deviation of external radiation exposure is approximately 200 uSv/y.

A third approach to deriving the de minimis level from background data is that the de minimis value should be a percentage (say 30%) of natural background (Rossi, 1980). Since background varies with location, the de minimis value would depend on the area being studied. The calculated world average for external background radiation of 800 to 900 uSv/y (NIH, 1980) would thus indicate a de minimis level of about 250 to 300 uSv/y.

Difficulty could be faced by agencies whose jurisdictions are geographically large or diverse and which derive de minimis levels from background exposure levels. Since natural exposures vary from location to location, how would an agency equitably or

rationally determine background conditions? Similarly, if risk is used as the basis for determining de minimis values (as described in Section C.2), there are the issues of what is an insignificant level of risk and under what conditions is the risk insignificant.

While the use of background exposure may be useful in the determination of de minimis levels of radiation, it is much less helpful for many chemical substances. It has been argued that exposures to low doses of ubiquitous risk-producing agents (such as radiation, nitrosamines, and formaldehyde) are probably less harmful than exposures to uncommon agents, due to the likelihood of human defence or repair mechanisms against common risks. On this basis, comparisons with background may be inappropriate (Whipple, 1984).

C.4 Observed Biological Effects

The lack of clinical evidence of health detriment from small exposures and low dose rates has made it necessary to extrapolate downward from the observed effects of large doses or high dose rates. The most commonly used model for this purpose is the linear, no-threshold, dose-effect relation which assumes that the risk is directly proportional to the radiation dose whatever the magnitude of the dose. Based on evidence from many biological systems and theoretical calculations, most radiobiologists believe that this model leads to an overestimation of the health effects of small doses especially for low linear-energy-transfer radiation such as gamma rays or low energy beta particles. A relatively small group of scientists believe there may be circumstances that lead to underestimation of effects when the linear model is used.

While many researchers believe it likely that there is no

absolute threshold for carcinogenic risks, some have suggested that there may be a "practical threshold dose" below which the incidence of radiation effects is extremely low because the tumour appearance time (latent period) increases as the dose decreases and may exceed the maximum human life span (Evans, 1974). The existence of such a threshold would provide guidance in the selection of a de minimis dose level.

The ability of cells to sustain hits up to a certain size from radiation particles without being permanently harmed is the basis for a new concept called "hit-size effectiveness function". The existence of a threshold or a "quantal response" could explain distinctly observable consequences such as the colour mutations that have been observed in certain plant cells. Investigators at Brookhaven National Laboratory estimate that a threshold for the mutations occurs around 2000 electron volts deposited per cell and intend to determine if the concept also applies to mammalian cells (Belford, 1984). If established, this approach would alter the dose-response curves currently used in radiobiology and support the presence of a dose which could, in turn, be used to define a de minimis level of exposure.

For carcinogenic non-radioactive substances, the possible existence of thresholds has been alluded to, based on the presence of several body defence mechanisms (Pochin 1978b; Ames, 1983). These include the continuous shedding of the surface layer of the skin, stomach, cornea, intestine and colon; the presence of enzymes that protect cells from oxidative damage; and the presence of antioxidatives (noncarcinogens) in the human diet such as vitamin E, ascorbic acid, and selenium (Ames, 1983).

Other researchers have postulated the possibility of radiation "hormesis" - the hypothesis that low doses of radiation are actually beneficial to health, in contrast to the detrimental

effects observed at higher dose levels and dose rates. Statistically significant associations have been reported in the U.S. and China between natural background levels of radiation and cancer mortality rates; that is, cancer mortality rates are lower, on average, in areas higher radiation than in areas of lower radiation (Hickey et al., 1983).

Several radiation studies on small mammals have been interpreted to indicate that exposure to long-term radiation, in the order of 0.1 to 1 Sv delivered over months, may extend the average life span of test animals by small amounts (Bond, 1981; Luckey, 1980). Other environmental agents are known to have different effects at low and at high doses. For example, many of the essential human nutritional elements are beneficial, even necessary, to health at low doses, but are toxic at high dose (Sagan, 1981), while repeated exposures to low doses of some substances such as arsenic lead to the development of resistance to high dose effects (Scientific Committee of the Food Safety Council, 1980).

APPENDIX D ANNOTATED BIBLIOGRAPHY OF SELECTED MATERIALS

Brief notes have been prepared for selected materials that were judged by team members to make substantial contributions to the study. The authors of the selected items represent several disciplines and perspectives. The items are presented in the following order:

- article by B. Ames, "Dietary Carcinogens and Anticarcinogens"
- article by P. Bunyan et al., "Impact of Risk Assessment and the Control of Chemicals on Assuring the Safety of the Food Supply"
- three papers in the book edited by W. Cragg, "Contemporary Moral Issues"
- report by J. Davis, "The Feasibility of Establishing a De Minimis Level of Dose and a Regulatory Cut-Off Policy for Nuclear Regulation"
- book by E. Efron, "The Apocalyptics"
- book by B. Fischoff et al., "Acceptable Risk"
- article by I. Munro and D. Krewski, "Risk Assessment and Regulatory Decision Making"
- paper by P. Taylor, "The Ethics of Respect for Nature"
- paper by C. Whipple, "Application of the De Minimis Concept in Risk Management"

Ames, B.N., 1983. "Dietary Carcinogens and Anticarcinogens." Science, Vol. 221, pp. 1256-1263.

This noted cancer researcher reviews the apparent ubiquity of known and suspected carcinogens and noncarcinogens in the environment. With the recognition of rapidly growing numbers of naturally-occurring carcinogens in plants and animals, the study of human dietary patterns is identified as a promising area of cancer research that might lead to an understanding of why there are wide differences in the rates of many types of cancer in different countries.

That nature is not as benign as was once believed is well documented. For example, the human dietary intake of "pesticides" naturally produced by plants for their protection amounts to about 10,000 times that of man-made pesticides. Despite such large exposures to naturally-occurring carcinogens, little is known about the toxicology of most natural plant toxins.

Since the avoidance of carcinogens is impossible, the author suggests that health protection should adopt a philosophy of risk management. He suggests the presence of several cancer defence mechanisms such as shedding of the skin's surface layer and the presence of antioxidatives in the diet, and speculates that a decrease in age-specific cancer rates in primates may have contributed to the increase in the average life spans experienced over the past 60 million years.

Bunyan, P.J., Coomes, T.J. and Elton, G.A.H., 1984. "Impact of Risk Assessment and the Control of Chemicals on Assuring the Safety of the Food Supply." Fundamental and Applied Toxicology, Volume 4, Number 3, Part 2 of 2 Parts. pp. S263-S277.

This paper reviews the current approaches to regulating food safety and associated risk-management issues in the United Kingdom. The authors come to the conclusion that it is difficult to establish by observation of man whether continued exposure can cause adverse effects in man, and that a history of prior exposure only provides evidence of safety if it is in the form of an epidemiological study.

In the U.K., the presence of pesticide residues in food falls under the Preservatives in Food Regulations. Recognizing that the presence of any residue would constitute an offence, there is a clause which allows the presence of pesticide residue in food if it can be proved that the substance's presence is due solely to its use as a food protector while it is in storage in any place other than where food is packed for retail sale.

Risk assessment is characterized as being an art, not a science. Using the food surveillance program which has been in place for the past decade, the U.K. approach to risk management is recognized as being incapable of giving absolute assurance of "safety" or zero risk. It is designed to avoid risk insofar as this is possible or practical in the light of the best scientific data and assessment available at any given time.

It is suggested that advances in evaluative science should be accompanied by a developing societal understanding of risk assessment in the food area. It is essential that changes in risk assessment, food supply and safety, or scientific interpretation should have the confidence of the public.

Cragg, W., (ed.), 1983. Contemporary Moral Issues. McGraw-Hill Ryerson.

The section entitled "Uranium Mining" consists of the editor's commentary and the following three papers:

Brook, J.A., 1983. "Uranium Mine Tailings and Obligations to Future Generations." The author argues that it is not morally permissible to discount future generations when assessing our obligations to manage uranium tailings and that our obligations should be determined by assessing broadly defined costs (risks) and benefits, and taking into account all persons, present and future. The paper attempts to develop the necessary conceptual apparatus for assessing the moral implications of a wide variety of waste management problems.

Narveson, J., 1983. "Moral Philosophy - What it is and Why it Matters." The case is made for taking moral philosophy into account when making policy decisions on the grounds that policy decisions are moral decisions. The author argues that we are morally obliged to do only what we have contracted (implicitly or explicitly) to do, and therefore that we have a far greater liberty, morally, than is usually perceived. In particular, we have no obligation to future generations, since we have no contract with them.

Levy, E., and Copp, D., 1983. "Risk and Responsibility: Ethical Issues in Decision-Making." The authors argue that it is impossible to determine the obligations we have with respect to a given risk on technical and scientific data alone, because the facts do not settle what we must and should do.

All three papers arose in the context of uranium mining issues and contain additional bibliographies.

Davis, J.P., 1981. "The Feasibility of Establishing a "De Minimis" Level of Radiation Dose and a Regulatory Cut-off Policy for Nuclear Regulation". Prepared for the Edison Electric Institute by General Physics Corporation.

This report summarizes approaches that had been proposed (up to the end of 1981) for determining levels of radiation dose that can be considered "negligible". It discusses how such levels could be applied to setting regulatory cut-off levels, below which exposure to radiation need not be considered. The report concludes that determination of a de minimis level based on comparison with background levels is feasible and could be an appropriate basis for establishing regulatory levels.

While much of the report addresses the de minimis concept from a U.S. perspective (in terms of legal interpretation, integration with existing regulation, and regulatory agency policies), the information concerning technical considerations, health effects and background risks and exposures, is equally relevant elsewhere.

The author has subsequently presented testimony before the U.S. Advisory Committee on Reactor Safeguards in the form of the brief "The De Minimis Regulatory Cut-Off Concept" (1984). Much of the 1981 report is reiterated in the testimony, although more details are provided as to how to implement the de minimis cut-off concept (in the U.S.) and the economic benefits it might provide.

Efron, E., 1984: The Apocalyptics. Simon and Schuster Inc.

This is an extensively researched review of the health protection policies of U.S. regulatory agencies and major organizations from several other countries. The policies are shown to be based largely on assumptions of questionable validity. Much of the book is aimed at numerous apparent inconsistencies and misrepresentations that underly cancer research and protection policy.

Numerous examples are presented that cast doubt upon the following key components of regulatory philosophy:

- laboratory test organisms can serve as surrogates for man;
- the no-threshold hypothesis;
- the one molecule theory;
- the precedence given to positive carcinogenesis data; and
- the policy of protecting all members of society.

Despite the weaknesses in the sciences of cancer research and the data they have produced, certain opinions have gained widespread acceptance:

- Most man-made chemicals violate the balance of nature and are carcinogens.
- Man-made chemicals cause most of the cancers in industrialized countries.
- Nature's role in the occurrence of cancer is unimportant.
- Science is capable of conclusively identifying carcinogens.

To the author, all these factors have combined to give an apocalyptic vision of a widespread outbreak of cancer soon to occur in industrialized countries due to man's activities. This apocalypse arose from a small, vocal group of scientists who entered into political action in the 1960's and whose warnings resulted in the creation of several laws and regulations in the

1970's which "liberated scientists from being scientists and allowed incompetents, opportunists and gurus to come in." As a result, regulators are now in pursuit of "ideological goals in the guise of the quest for truth" while the public is misinformed and not encouraged to look at the issues reasonably or objectively.

Important questions raised by the author include:

- Would the no-threshold hypothesis or the one molecule theory have been developed if natural carcinogens were studied before synthetic chemicals?
- In their efforts to protect the public, have regulators replaced science with ideology, chosen to overlook scientific evidence that contradicts their beliefs, and set impossible goals?

Fischoff, B., Lichtenstein, S., Slovic, P., Derby, S.L., and Keeney, R.L., 1981. "Acceptable Risk". Cambridge University Press.

This book, which arose out of work done for the nuclear industry in the United States, is a comprehensive and yet elementary attempt to lay out the main options for assessing risks. It distinguishes three main approaches: professional judgement, bootstrapping (i.e. assessing a new risk against some risk which we already accept) and formal analysis. It concludes that there is no single best road to risk assessment, and lays out the work that needs to be done to assess a risk competently.

Munro, I.C. and Krewski, D.R., 1981. "Risk Assessment and Regulatory Decision Making". Food and Cosmetics Toxicology, Vol. 19, pp. 549-560.

The role of risk in the development of regulatory policy is

reviewed with an emphasis on its role in toxicology. The authors, at the time both members of the Food Directorate, Health and Welfare Canada, note that risk has always been an integral component of life but that the transition to an urban society and advances in biological science have shifted public perceptions of risk acceptability.

Current scientific debate centres around the use of mathematical models to evaluate risks of low doses of human exposure. The most frequently used models are directed towards identifying virtually safe doses. All models fit equally well the data in the observed ranges but give widely different risks in the extrapolations to low level exposures. The present inability to assess the risks of low level exposures is the source of serious problems to regulatory agencies; nevertheless, the use of models holds more promise than the historically used no-observed-effects limits and safety factors.

The authors conclude that:

- risk cannot be eliminated at the cost of compromising food supplies, facilitating the spread of disease, or lowering overall environmental quality;
- the rapid rate at which carcinogens are being discovered in the environment and the increased consumer awareness, indeed fear of cancer, is prompting regulators to re-evaluate food-safety policies;
- it is counterproductive to introduce regulations that can't be enforced;
- consumer expectation strongly influences safety in Canada; and ,
- scientists and regulators must not delude themselves or the public into thinking that risk assessment will produce clear-cut instructions for the decision-making process.

Taylor, P., 1981. "The Ethics of Respect for Nature". Environmental Ethics, Vol. 3, Fall 1981, pp. 197-218.

The basic paper in the approach which argues that not just people but nature as a whole deserves moral respect when we are deciding what we must do and what it is permissible not to do. Taylor argues that anything which has a good of its own (i.e. roughly a capacity to be harmed or benefited) has intrinsic worth, and so is worthy of moral concern. He acknowledges that his argument for the last step is not as conclusive as some might like.

Whipple, C., 1984. "Application of the De Minimis Concept in Risk Management." Paper presented to a joint session of the American Nuclear Society and Health Physics Society, New Orleans, LA., 27 pages.

The author, a representative of the Electric Power Research Institute presents a succinct review of the potential application of the de minimis concept to regulatory philosophy. While many examples relate to radiation exposure, the author also makes frequent reference to non-radioactive substances.

The incentives to explicitly establish the de minimis concept in regulations are seen as coming from several sources:

- technologies have improved and now can identify small risks;
- fast, inexpensive tests have shifted society's perception of low level risks; risks are pervasive and cannot be totally eliminated; therefore, there is a need to "manage" carcinogens;
- case-by-case regulatory decisions involving low level exposures are cumbersome;
- the de minimis concept would improve regulatory stability and predictability and therefore is supported by industry;
- regulators support the concept because they would be

relieved from making judgements in unknown areas;
- several recent court decisions can be interpeted as acknowledging the need for the concept.

The author suggests a three-component format for using the de minimis concept to take into account both individual and societal considerations of risk. One troubling aspect of the concept is whether or not all risk agents will be addressed since it would hardly be comforting to learn that, although no single chemical in drinking water poses a risk in excess of 10^{-7} per year, there were 10^{6} such chemicals.

The author stresses that:
- the de minimis concept is not new; what is new is its explicit use to replace its ad hoc or pragmatic use;
- social values judgement will define de minimis risks;
- it may be better to define de minimis risks as those with "too low a priority to regulate" rather than being "acceptably low"; and
- more attention should be directed towards the aggregation of multiple risks.

APPENDIX E SUGGESTED TOPICS FOR FUTURE RESEARCH

During the course of this study, several aspects of the de minimis concept that might merit further consideration and research were identified by team members. The following examples have been organized under the headings of technical, administrative and ethical considerations. In large measure, the examples represent those topics that lie outside the project's scope first referred to in Section 1.4.

Technical Considerations

- The definition of de minimis as it applies to uranium tailings management needs to be improved upon, the goal being to fashion a succinct, readily-apparent meaning.
- Further efforts need to be spent quantifying trivial risks and relating de minimis to risk judgement.
- The conditions under which truncation is necessary and the proper application methodology need to be defined.
- Better methods are needed for the calculation of collective detriment.
- Proper ways need to be developed for the identification, agglomeration, and interpretation of the implications of multiple sources of trivial risks.
- The use of de minimis values in probabilistic assessments of uranium tailings management which generate distributions of dose should be investigated.

Administrative Considerations

- The general public and regulators must become more familiar with the concept of acceptable risk and its role in law.

- Regulators should develop an appreciation for the roles and magnitudes that uncertainty and variance play in the interpretation of information.
- The implications that the explicit incorporation of the de minimis concept into some legislation might have on other laws and legislation need to be investigated.
- A better appreciation of current public attitudes is needed by regulators and regulatory advisors.

Ethical Considerations

- Who or what has moral standing, and identifying what is in the best interests of those with moral standing are unresolved issues.
- The ways in which social organization influences perceptions of risk and benefit are largely unstudied.
- Since individuals make many decisions that directly influence the type, magnitude and frequency of risks in their lives, should part of the responsibility for defining or instituting de minimis risks be left with the individual?
- How can the various distributional issues be resolved in an ethical and optional way? How should this affect society's allocations of resources?

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QUALITY
ORIGINAL